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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

[60Day-12-0010]

Proposed Data Collections Submitted for
Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 and send comments to Kimberly Lane, CDC Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

The National Birth Defects Prevention Study (NBDPS), (OMB 0920-0010) - Reinstatement Without Change- National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC has been monitoring the occurrence of serious birth defects and genetic diseases in Atlanta since 1967 through the Metropolitan Atlanta Congenital Defects Program (MACDP). The MACDP is a population-based surveillance system for birth defects in the 5 counties of Metropolitan Atlanta. Its primary purpose is to describe the spatial and temporal patterns of birth defects occurrence and serves as an early warning system for new Teratogens.

The National Birth Defects Prevention Study (NBDPS) formerly the Birth Defects Risk Factor Surveillance Study (BDRFS) began in 1997. The NBDPS is a case-control study of major birth defects that includes cases identified from existing birth

defect surveillance registries in nine states, including metropolitan Atlanta. NBDPS control infants are randomly selected from birth certificates or birth hospital records. Mothers of case and control infants are interviewed using a computer-assisted telephone interview. The interview takes approximately one hour to complete. A maximum of four hundred interviews are planned per year per center, 300 cases and 100 controls resulting in a maximum interview burden of 400 hours for each of the centers each year.

Parents are also asked to collect cheek cells from themselves and their infant for DNA. The collection of cheek cells by the mother, father, and infant takes about 10 minutes per person. Each person rubs 1 brush inside the left cheek and 1 brush inside the right cheek for a total of 2 brushes per person. Collection of the cheek cells takes approximately 1-2 minutes, but the estimate of burden is 10 minutes to account for reading and understanding the consent form and specimen collection instructions and mailing back the completed kits. The anticipated maximum burden for collection of the cheek cells is 200 hours per center per year.

Information gathered from both the interviews and the DNA specimens have been and will continue to be used to study independent genetic and environmental factors as well as gene-

environment interactions for a broad range of carefully classified birth defects.

This request is submitted to obtain OMB clearance for three additional years.

There are no costs to the respondents other than their time.

Estimated Annualized Burden Hours per Center

Respondents	Number of Respondents	Number of responses per respondent	Avg. burden per Response	Total Burden Hours
NBDPS case/control interview	400	1	1	400
Biologic Specimen Collection	1,200	1	10/60	200
Total				600

DATE:

Kimberly S. Lane,
Acting Reports Clearance Officer

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